Spire Biomedical, Inc. • One Patriots Park • Bedford, MA 01730-2396
(781) 275-6001 • (781) 275-6010 fax

JUL 19 2002

SECTION 7

510(K) Summary

Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (with and without side holes)

Date: June 18, 2002

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
Phone: (781) 275-6001
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Contact Person:
Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
Phone: (781) 275-6001 x221
Fax: (781) 275-6010
e-mail: dfickett@spirecorp.com

Device Names:

Trade Name: Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Common Name: Catheter, Intravascular, Long-Term

Classification Name: Catheter, Hemodialysis, Implant (Long-Term)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Spire Biomedical, Inc. Pourchez XpressO™ (K013160 and K021212)
2) Kendall Tandem-Cath™ (for dynamic and static flow comparison – K002902)

Device Description: The Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is a flexible radiopaque silicone catheter. The distal end has two tips separated over a predetermined distance. The distal arterial and venous lumens are round and are staggered to reduce recirculation. The body is oval, and the proximal end, which is connected to the catheter body by color-coded extension adapters, has two distinctive lumens with color-coded adapters (red for arterial and blue for venous). The catheter is available in five different implant lengths. It is also available with and without side holes on the distal ends. The catheter has a polyester cuff located at one of five different implant lengths from the distal end.

A RetrO catheter repair kit will also be offered to replace damaged extensions and/or extension adapters.

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510(K) Summary
(Continued)

Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips (with and without side holes)

Intended Use

The indicated use and indications of the Pourchez RetrO™ catheter have not changed. It is designed for chronic (long-term) hemodialysis and apheresis. It is designed for percutaneous insertion or insertion via cutdown into the jugular or subclavian vein.

Technological Characteristics Comparison to Predicate Devices

The Pourchez RetrO™ Catheter has the same materials of construction, intended use, implant lengths, number of lumens, cross-sectional lumen area, insertion method and insertion sites, blood recirculation and mechanical hemolysis rates, and sterilization methods as the Pourchez XpressO™ Catheter.

Each catheter is 52cm overall with the usable lengths marked every 5cm to 50cm. The extensions are connected to the catheter body using color-coded (red for arterial and blue for venous) locking connectors made of same material used for the luer adapters.

Additionally, the Pourchez RetrO™ catheter has similar flow rates and priming volumes as the Kendall Tandem™ catheter.

Performance Data

A series of tests were performed to demonstrate substantial equivalence to predicate devices or conformation to established ISO standards for hemodialysis catheters. In all cases, the Pourchez RetrO™ catheter demonstrated equivalent performance to the predicate devices and acceptance criteria established by the appropriate standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Mr. Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730-2396

Re: K022000
Trade/Device Name: Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: June 18, 2002
Received: June 19, 2002

Dear Mr. Fickett:

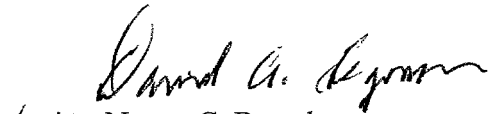
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4610. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022000

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APPENDIX B – Indications for Use Statement

Device Name: Pourchez RetrO™ Twin Lumen Chronic Hemodialysis Catheter with Separated Tips

Indications for Use: Spire Biomedical, Inc.'s Pourchez RetrO™ Silicone Twin Lumen Chronic Hemodialysis Catheter with Separated Tips is designed for chronic hemodialysis and apheresis. It is a radiopaque silicone catheter designed for percutaneous insertion or insertion via a cutdown.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Optional Format 3-10-98)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022000